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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JENKINS, WILSON, TAYLOR & HUNT, P. A.
Suite 1200 UNIVERSITY TOWER
3100 TOWER BLVD.,
DURHAM, NC 27707

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
06/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,496	FRANZEN ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 38-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36 and 38-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12 & 29 May 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 May 2009 has been entered.

Drawings

2. The drawings were received on 12 May 2009. These drawings are not acceptable.

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because:

a. Figures 1-3 and 5-16 are not properly labeled. As set forth under 37 CFR 1.84(u)(1): "View numbers must be preceded by the abbreviation 'FIG.'"

b. FIG. 17 is not properly labeled as each panel needs to be individually labeled, e.g., FIG. 17A, FIG. 17B. As required by 37 CFR 1.84(u)(1): "Partial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter."

4. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-36 and 38-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of

> the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary

The quantity of experimentation necessary is great, on the order of several man-years, and then with little if any reasonable expectation of successfully enabling the full scope of the claims.

The amount of direction or guidance presented,

The amount of guidance provided is limited, generally prophetic, and not commensurate with the scope of the claims.

The presence or absence of working examples

The specification has been found to comprise the following examples:

- Example 1, pp. 57-59, "X-Ray Photoelectron Spectroscopy Characterization of ITO Electrode Surfaces Modified By Single Stranded DNA And Gold Nanoparticles;"
- Example 2, p. 59, "Infrared Reflection Absorption Spectroscopy (IRRAS);"
- Example 3, p. 60, "LITJ At Gold Nanoparticle-Coated ITO Electrodes;"
- Example 4, p. 61, "Infrared Thermography Of Gold Nanoparticles;" and
- Example 5, p. 62, "DNA Detection With Infrared Thermography."

Of the five examples provided, Example 5 relates to the claimed invention. Upon review of the example, it is noted that no reaction conditions or starting materials are provided. The situation

at hand is analogous to that in *Genentech v. Novo Nordisk A/S* (Fed. Cir. 1997) 42 USPQ2d 1001. As set forth in the decision of the Court:

> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

The nature of the invention

The invention relates to the detection of nucleic acid hybridization reactions based solely upon an infrared signature generated by a nanoparticle attached to a probe.

The state of the prior art & The breadth of the claims

The state of the art has advanced to the point that numerous issues of operability are now known to exist. As presently worded, the method fairly encompasses the detection of multiple target nucleic acids in a simultaneous manner, yet but a single nanoparticle is to be used. Assuming *arguendo*, that one can detect an infrared signature of an illuminated nanoparticle, one would not be able to differentiate which target is present, or whether any and all of the targets are present.

While claim 45 has been amended so to recite specific reaction conditions, such does not preclude the use of multiple probes against multiple targets and detecting a common nanoparticle.

While independent claims 1 and 44 have been amended so to recite limitation that "the capture probe selectively hybridizes to the target nucleic acid," such a limitation does not effectively add any limitation to the claims as nucleic acids bind in a competitive manner selecting those that have a higher coefficient of attraction. Such a limitation does not, however, preclude the same probes from binding to other nucleic acids that have a lower coefficient of attraction, e.g., hybridization to a nucleic acid that is less than fully complementary. Indeed, the claimed method does not require that the probes be fully complementary to any target sequence. In support of this position, it is noted that the probe need be "complementary in whole or in part to the target nucleic acid" (claim 1, line 9). So even in light of these added limitations, one would still be unable to differentiate between those duplex or triplex structures that are intended to form over that which are undesired.

The specification is wholly silent as to how one would apply the claimed method to the detection of point mutations, much less inversion or translocations, when, for example, the target nucleic is a chromosome. In support of this position, it is noted that the target nucleic acid of claim 1 can be of any length. Further, page 16 of the specification defines the target nucleic acid as being of any length. While page 16 of the specification does identify lengths far shorter, such limitations have not been read into the claims. It is noted with particularity that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. *In re Philips Industries v. State Stove & Mfg.*

Co, Inc..., 186 USPQ 458 (CA6 1975). While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

In accordance with claim 1, one is to employ a nanoparticle that is capable of absorbing light at any wavelength. While the claim 1 sets an upper limit of 1,000 nm, there is no lower limit. A review of the specification fails to find where applicant has provided an adequate written description of the genus of such "nanoparticles," much less enabled the use of same.

The claimed method is to result in the detection of a nucleic acid. The nucleic acid can be of any nucleotide sequence, from any source, including that which is unknown, and of no known utility. The specification is silent as to how the information of detection is to be used. While the claims are directed to the detection of a nucleic acid, and not to the use of the information so generated, the specification still must enable the use of the product of the method, which in the instant case is information. Such an enabling disclosure has not been found.

In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- US Patent Application Publication 2003/0003300A1 (Korgel et al.), at paragraph [0010], discloses nanoparticles may emit light in IR spectrum; and at paragraph [0169] use such nanoparticles in analysis of DNA, RNA, etc.
- US Patent Application Publication 2002/0103517A1 (West et al.), at paragraph [0008], discloses coupling nanoparticles to a variety of compounds; that nanoparticles can be selected so to absorb at any of a variety of wavelengths and that they have a "tunable" excitation wavelength. West et al., disclose that their optically-active nanoparticles can be used in diagnostic applications.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634